K072395

JAN - 3 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter's name:	Diazyme Laboratories
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Name of Contact Person:	Charles Yu Diazyme Laboratories 12889 Gregg Court Poway, CA 92064 Phone: 858-455-4761 Fax: 858-455-4750
Date the Summary was Prepared:	August 20, 2007
Name of the Device	Diazyme HDL-Cholesterol Reagent
Trade Name:	Diazyme HDL-Cholesterol Reagent
Common/Usual Name	Lipoprotein Test System
Device Classification Name	High Density Lipoprotein Cholesterol Test
Product code:	LBS, JIS
Submission Type	510k
Regulation Number	862.1475
Device Class	II
Predicate Device:	For the Lipoprotein test system, we are claiming equivalence [807.92(a) (3) to HDL ULTRA CHOLESTEROL REAGENT (k021316) manufactured by Genzyme Diagnostics

Substantial Equivalence Information

1. **Predicate device name(s):**

   Ultra N-Geneous HDL Cholesterol Reagent

2. **Predicate 510(k) number(s):**

   k021316

3. **Comparison with predicate:**

Indications for Use

Diazyme HDL-Cholesterol Reagent	Ultra N-geneous HDL Cholesterol Reagent	Equivalency
The Diazyme HDL-Cholesterol reagent is intended for the in vitro quantitative determination of High Density Lipoprotein Cholesterol in human serum or plasma. The reagents can assist in the diagnosis and treatment of patients at risk of developing coronary heart disease. Low HDL cholesterol is related to the high risk of coronary heart disease.	For the quantitative determination of high density lipoprotein cholesterol (HDL-C) in human serum or plasma.	Same

Principle

Diazyme HDL-Cholesterol Reagent	Ultra N-geneous HDL Cholesterol Reagent	Equivalency
The assay is based on a modified polyvinyl sulfonic acid (PVS) and polyethylene-glycol-methyl ether (PEGME) coupled classic precipitation method with the improvements in using optimized quantities of PVS/PEGME and selected detergents[9]. LDL, VLDL, and chylomicron (CM) react with PVS and PEGME and the reaction results in inaccessibility of LDL, VLDL and CM by cholesterol oxidase (CHOD) and cholesterol esterase (CHER). The enzymes selectively react with HDL to produce H_2O_2 which is detected through a Trinder reaction.	This method is based on accelerating the reaction of cholesterol oxidase(CO) with non-HDL unesterified cholesterol and dissolving HDL selectivity using a specific detergent. In the first reagent, non-HDL unesterified cholesterol is subject to an enzyme reaction, and the peroxide generated is consumed by a peroxidase reaction with DSBmT yielding a colorless product. The second reagent consists of a detergent capable of solubilizing HDL specifically , cholesterol esterase(CE) and chromagenic coupler to develop color for the quantitative determination of HDL-C.	Similar

Test Objective

Diazyme HDL-Cholesterol Reagent	Ultra N-geneous HDL Cholesterol Reagent	Equivalency
For the in vitro quantitative determination of High Density Lipoprotein Cholesterol in human serum or plasma.	For the quantitative determination of high density lipoprotein cholesterol (HDL-C) in human serum or plasma.	Same

Type of Test

Diazyme HDL-Cholesterol Reagent	Ultra N-geneous HDL Cholesterol Reagent	Equivalency
Quantitative	Quantitative	Same

Specimen Type

Diazyme HDL-Cholesterol Reagent	Ultra N-geneous HDL Cholesterol Reagent	Equivalency
Human serum or plasma	Human serum or plasma	Same

Product Type

Diazyme HDL-Cholesterol Reagent	Ultra N-geneous HDL Cholesterol Reagent	Equivalency
Calibrator, Reagent, Instrument	Calibrator, Reagent, Instrument	Same

Performance

Diazyme HDL-Cholesterol Reagent	Ultra N-geneous HDL Cholesterol Reagent
Reportable linear Range: Serum: **1.06- 184.8 mg/dL** Precision/Serum: Within Run: **0.70% -1.10%** Total: **1.8%–3.7%** Accuracy/Serum: Correlation Coefficient: **0.987** Slope/Intercept: **y = 1.048x – 4.69 mg/dL**	Reportable linear Range: Serum: **2.5 – 200 mg/dL** Precision/Serum: Within Run: **0.5% -0.8%** Total: **1.1%–1.5%** Accuracy/Serum: Correlation Coefficient: **0.996** Slope/Intercept: **y = 0.99x + 2.81mg/dL**

Calibrator Comparison

Diazyme HDL Cholesterol Calibrator	Ultra N-geneous HDL Cholesterol Calibrator	Equivalency
Lyophilized form	Lyophilized form	Same
HDL Cholesterol calibrator is traceable to NIST SRM 1915b.	HDL Ultra Cholesterol calibrator is traceable to the National Reference System for Cholesterol (NRS/CHOL)	Same

Rationale for Considering the Device Substantially Equivalent to Devices Approved for Interstate Commerce

Genzyme Ultra N-geneous HDL Cholesterol Reagent (k021316) was selected for comparing serum samples with to the results generated by Diazyme HDL-Cholesterol Reagent. Detailed performance characteristics and comparison analysis are given in this filing and demonstrate substantial equivalence to predicate device that is currently being legally marketed.

The Diazyme HDL-Cholesterol Reagent is similar to the approved predicate test. The minor differences in the performances of the tests should not affect the safety and effectiveness of the Diazyme HDL-Cholesterol Reagent and offers users a rapid device to measure HDL Cholesterol in human serum or plasma.

In summary, the dissimilar features between the Diazyme HDL-Cholesterol Reagent and device currently legally marketed do not affect the safety or effectiveness of the device. This is supported by the accuracy data comparing serum sample values obtained using the Diazyme HDL-Cholesterol Reagent with those obtained using the predicate device, Genzyme Ultra N-geneous HDL Cholesterol Reagent (k021316).

Description of the Device

The assay is based on a modified polyvinyl sulfonic acid (PVS) and polyethylene-glycol-methyl ether (PEGME) coupled classic precipitation method with the improvements in using optimized quantities of PVS/PEGME and selected detergents. LDL, VLDL, and chylomicron (CM) react with PVS and PEGME and the reaction results in inaccessibility of LDL, VLDL and CM by cholesterol oxidase (CHOD) and cholesterol esterase (CHER). The enzymes selectively react with HDL to produce H_2O_2 which is detected through a Trinder reaction.

$$\text{HDL + LDL + VLDL + CM} \xrightarrow[\text{PEGME}]{\text{PVS}}$$

$$\text{HDL + (LDL + VLDL + CM)} \cdot \text{PVS/PEGME}$$

$$\text{HDL + CHOD + CHER} \longrightarrow \text{Fatty Acid} + H_2O_2$$

$$2H_2O_2 + \text{4-AA+TODB} \xrightarrow{\text{Peroxidase}} \text{Quenone} + 5\ H_2O \quad (\lambda_{max}=560\text{nm})$$

Intended Use of the Device:

The Diazyme HDL-Cholesterol reagent is intended for the *in vitro* quantitative determination of High Density Lipoprotein Cholesterol in human serum or plasma. The reagents can assist in the diagnosis and treatment of patients at risk for developing coronary heart disease. Low HDL cholesterol is related to the high risk of coronary heart disease.

Performance Characteristics

Diazyme HDL-Cholesterol Reagent is a homogeneous two-reagent enzymatic assay. The results are obtained in 10 minutes by measuring absorbance at 600nm. The linearity of the assay is from 1.06-184.8 mg/dL for Serum samples. The assay offers excellent precision as shown in the tables below:

Serum Testing	**Level 1 30mg/dL HDL**	**Level 2 55mg/dL HDL**	**Level 3 90mg/dL HDL**
Within-Run Precision	$C_V\% = 1.0\%$	$C_V\% = 0.8\%$	$C_V\% = 0.9\%$
Total Precision	$C_V\% = 2.3\%$	$C_V\% = 2.6\%$	$C_V\% = 2.2\%$

In method comparison studies, samples tested with Diazyme HDL-Cholesterol Reagent showed good correlation with Genzyme Ultra N-geneous HDL Cholesterol Reagent (k021316) with correlation coefficients of 0.985 for serum samples.

We have conducted interference studies by spiking normal pooled human serum samples with substances normally present in serum or plasma and found no interference at the indicated concentrations.

Interference Study	
Substance	**Concentration**
Triglycerides	1000 mg/dL
Ascorbic acid	10 mmol/L

Bilirubin	40 mg/dL
Bilirubin Conjugated	30 mg/dL
Hemoglobin	1000 mg/dL

Conclusion: Comparison analysis presented in this 510k submission filing in the comparison section, together with linearity, precision and interference and other detailed studies, demonstrates that the Diazyme HDL-Cholesterol Reagent has excellent accuracy and is safe and effective. There is no significant deviation between the results obtained by Diazyme HDL-Cholesterol Reagent and the legally marketed predicate device (k021316) when testing clinical patient samples and is therefore substantially similar. Comparison analysis presented in this 510k submission together with the stability data demonstrates that the Diazyme HDL-Cholesterol Reagent is substantially similar to legally marketed device (k021316).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 3 2008

Diazyme Laboratories
c/o Mr. Charles Yu
12889 Gregg Court
Poway, CA 92064

Re: k072395
Trade/Device Name: Diazyme HDL-Cholesterol Reagent
Regulation Number: 21 CFR§862.1475
Regulation Name: High Density Lipoprotein Cholesterol Test
Regulatory Class: Class I
Product Code: LBS, JJX
Dated: December 21, 2007
Received: December 27, 2007

Dear Mr. Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K072395

Device Name: Diazyme HDL-Cholesterol Reagent

Indications for Use: The Diazyme HDL-Cholesterol reagent is intended for the *in vitro* quantitative determination of High Density Lipoprotein Cholesterol in human serum or plasma. The reagents can assist in the diagnosis and treatment of patients at risk of developing coronary heart disease.

Calibrator: For calibration of the Diazyme HDL-Cholesterol Reagent Assay in serum or plasma.
For In Vitro Diagnostic Use

Controls: To monitor the performance of Diazyme HDL-Cholesterol Reagent.
For In Vitro Diagnostic Use

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol J Benson

...n Sign-Off

Office of In Vitro Diagnostic Device
...ation and Safety

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